

ESTABLISHMENT RESPONSIBILITIES FOR READY-TO-EAT (RTE) SANITATION

Objectives

Upon completion of this training, Consumer Safety Inspectors will be able to determine whether there is reason to question the sanitation of the ready-to-eat product processing environment.

Introduction

As regulators, you must have a general knowledge about the processes that the industry uses to produce safe products. It is important that you are aware of some of the sanitation issues essential to the production of safe RTE products. In this section we will discuss some of the establishment's responsibilities for sanitation in the RTE environment. Establishments producing RTE products have a special responsibility for sanitation because of the high risk of foodborne illness due to post-lethality contamination.

Before we go further, let's define some of these terms. **Ready-to-eat (RTE)** products have received a **lethality** treatment. The lethality treatment, generally a cooking procedure, must be designed to kill all of the pathogens, or harmful bacteria. This lethality treatment makes the product safe to eat by the consumer without any further treatment, and we normally refer to these products as "ready-to-eat."

Many RTE processes involve handling the product after it has received its lethality treatment (**post-lethality**). When the product is **directly exposed** to the environment it can become cross-contaminated. **Cross-contamination** is the transfer of bacteria and possibly pathogens to the exposed RTE product after the lethality treatment. These bacteria can come from the environment, from the employees, or from the equipment. They can be transferred directly, such as when an exposed RTE product is placed on a table top which has bacteria on it. Often they are transferred indirectly, such as when a pallet placed on the floor in the raw area is subsequently used in the cooked area, or when an employee handles a pallet and then touches exposed product.

Many RTE products are taken right from the package and consumed as they are, with little or no heat treatment. If any pathogens are present, they will be consumed along with the product. Thus the risk of these products producing foodborne illness is increased. Because of this, establishments producing these products have an increased responsibility for sanitation of the RTE production area.

RTE Sanitation

Sanitation is critical for ensuring that RTE products do not become cross-contaminated. Sanitation Standard Operating Procedures (SSOPs) should be established to provide effective and consistent results. Effective sanitation is a complex process. A successful establishment must understand and apply the cleaning and sanitizing process and select the proper methodology and chemical agents for the particular environment and equipment being cleaned. RTE sanitation may include the following steps.

- a) Dry/waterless cleaning, removing large debris
- b) Pre-rinsing equipment
- c) Foaming and scrubbing
- d) Rinsing
- e) Visual inspection of equipment
- f) Sanitizing
- g) Drying

Cleaning consists of removing the soil from the equipment and environment. The “soil” in this case is product residue, which provides nutrients for bacterial growth.

Sanitizing is the application of either heat or chemicals to substantially reduce the numbers of microorganisms to an acceptable level. In some situations, the acceptable level for a specific pathogen is zero. Sanitizing is done after cleaning, because a sanitizer can not work unless the equipment is cleaned first. Chemical solutions commonly used are chlorine, iodophors, or quaternary ammonium compounds. To be effective, the sanitizer must be applied at the appropriate temperature and concentration for the proper length of time. Heat, usually in the form of hot water, is also sometimes used to sanitize.

Rotating sanitizers is generally a good practice as it will provide greater effectiveness against bacteria. Some establishments rotate sanitizers by using one for a certain time period, and then switching to another. Another way to rotate sanitizers is to use them for different applications, for example, using one on equipment and a different one in boot dip stations. Alternating between alkaline-based detergents and acid-based detergents also helps to avoid “soapstone” or hard-water buildups. Alternating detergents helps change the pH regularly to prevent adaptation of bacteria to a particular environment. Therefore rotating sanitizers can help prevent formation of biofilms. A **biofilm** is a thin layer of microorganisms that essentially glue themselves together in order to adhere to the surface of equipment or other structures. Because of the nature of this film, the bacteria are difficult to remove and are protected from chemicals used to clean and sanitize surfaces.

Listeria monocytogenes

Establishments are responsible for producing product that is free from any pathogen. However, one strain of the *Listeria* species, the pathogen *Listeria monocytogenes* (*Lm*), is of particular concern because it has potentially fatal consequences. *Lm* is especially pathogenic to high-risk populations, including pregnant women, newborns, elderly, and people with weakened immune systems. *Lm* is found in the intestines of healthy animals (including humans) and in the environment in which food-producing animals are raised and processed, for example, in soil, water, and vegetation. *Lm* can also be found in the food processing environment, on the surfaces of equipment, floors, walls, overhead structures, etc.

Lm is spread very easily by direct contact with a contaminated surface. *Lm* can survive and grow in cool, damp environments such as those found in process areas, coolers, or floors. Incomplete removal of product debris can provide nutrients and a place of attachment which allows bacterial growth. *Lm* can form biofilms on solid surfaces such as stainless steel and rubber, and can survive adverse conditions on apparently smooth surfaces.

Lm is more heat resistant than most foodborne bacterial pathogens and also can survive freezing and drying. *Lm* is very hardy. It can survive and grow in refrigerated, packaged, ready-to-eat products and resists high salt levels, nitrite, and acid. In addition, it can grow in vacuum packaged products. Thus, it is vitally important for an establishment to maintain strict sanitary controls to prevent the organism from contaminating products.

Foodborne illnesses and deaths have been linked to some recalled products adulterated with *Lm*. It has generally been concluded that the adulteration occurred through cross-contamination from environmental sources after cooking.

Listeria monocytogenes in the Plant Environment

Plants must focus on preventing contamination of RTE products with *Lm*. *Lm* can be introduced by contaminated food contact surfaces, by employees, or by environmental reservoirs. Cross-contamination occurs when a cooked, exposed product directly contacts a surface that has been contaminated with *Lm*. In order to prevent cross-contamination, establishments need to ensure that sanitation is effectively maintained, with special attention being given to those areas where product is stored or handled after lethality has been applied to the product.

Sanitizers that have proven most effective against *Lm* are quaternary ammonia compounds, chlorine solutions and newer products containing peracetic acid.

Because this organism needs moisture to grow, keeping storage and production areas and equipment as dry as possible helps reduce the opportunity for *Listeria* to reproduce. For example, product contact equipment, and production area floors should be maintained free of standing water and kept as dry as possible.

Listeria monocytogenes and Construction

Lm contamination has been linked with disruptions in the production process or environment. In particular, disruptive construction (e.g., breaking out walls or other activities that can generate dust) has been shown to have a clear association with *Lm* contamination of both product and the surrounding environment. *Lm* can survive in moist, enclosed areas of the environments, such as cracks in walls and floors, and in crevices around drains; often these areas are disturbed during construction.

Dust generated by construction and other disruptive activities can establish contamination on food contact and other environmental surfaces. For example, dust can travel throughout the plant on air currents or be transferred by people or equipment traveling through the construction area into other areas of the establishment. Dust from construction can be difficult to detect and control. Therefore, increased monitoring of product, food-contact surfaces, and the environment is recommended **during and after** these disruptive events.

Some examples of hazardous construction activities include:

- Removal of drains
- Removal of floor coatings
- Removal of a wall or ceiling that has absorbed moisture
- Movement through an RTE area of potentially contaminated materials
- Exposure of an area typically not accessible for cleaning

Establishments have the responsibility to control establishment activities during construction in order to ensure that only safe food is produced. When construction is necessary, there are several solutions that establishments may employ. Establishments may establish negative air pressure in the construction area in order to ensure that air does not flow from the construction area into the plant. Temporary partitions can be established to protect the undisturbed areas of the plant from construction dust and debris.

Possible Post-Cooking Contamination Sources—Direct Product Contact

Cleaning and sanitizing are very important. Pathogens can be transferred to RTE products from equipment that has not been adequately cleaned and sanitized.

Protecting RTE product during processing procedures and as it moves throughout the plant is an important consideration in possible post-cooking contamination. Products that are inadequately packaged or covered or contained in damaged packaging could become contaminated. Packaging or covering used to protect RTE products during processing and storage should be adequate for preventing the entry of contaminants.

Personnel hygiene practices are essential to prevent RTE cross-contamination. Pathogens could be present on the hands of workers handling the food. The hands are particularly important in transmitting foodborne pathogens. Workers with dirty hands or fingernails may contaminate the food being prepared. Any activity which may contaminate the hands must be followed by thorough hand washing. Examples of activities which may contaminate the hands include using toilet areas, picking up any item on the floor, handling boxes, and touching door handles or other hand-contact devices. The hands of employees can be contaminated by touching their nose or other body parts. Hand washing is a critical factor in reducing pathogens that can be transmitted from hands to RTE products. Many employees fail to wash their hands as often as necessary and even those who do may use flawed technique.

Examples of post-cooking contamination sources:

- Solutions to chill foods, brine solutions
- Slicers, dicers, saws
- Casing peelers
- Lugs, tubs, containers
- Hand tools
- Packaging materials and equipment
- Tables, conveyors, belts
- Door pulls and equipment controls (employee hand contact areas)
- Employees: clothing, gloves, aprons or boots
- Employee hygiene practices

Potential Reservoirs In The Environment — Non Product Contact

Processing activities may expose the RTE product to an environment that may lead to the product's contamination. Products must be protected during processing. Workers' shoes can carry contamination onto the floors of food preparation and storage areas. Even trace amounts of refuse or wastes in rooms used as toilets or in rooms used for storing trash or housing equipment can become sources of food contamination. Moist conditions in storage areas promote microbial growth. Sources of environmental contamination may include splash from cleaning operations, drips from overhead ventilation units, or air from an insanitary atmosphere. Bacteria can be conveyed considerable distances on air currents through fine sprays or aerosols. This could originate, for example, from a water spray directed at a drain. Ice that has been in contact with unsanitized surfaces or raw meat or poultry products may contain pathogens. If this ice contacts RTE products or food-contact surfaces it could contaminate the final product.

Examples of environmental reservoirs:

- Floors and drains
- Standing water, e.g., in overhead drip pans
- Ceilings and overhead pipes
- Refrigeration units
- Wet insulation
- Equipment motor housings
- Cleaning tools: mops, brushes, squeegees or other utensils
- Overhead rails and trolleys
- Maintenance tools
- Pallets
- Forklifts
- Any recessed or hollow material: rollers, switch boxes, motor housing
- Rusted materials
- Cracked or pitted rubber hoses or seals
- Walls that are cracked or pitted, and inadequately sealed surfaces
- Vacuum or air pressure pumps, lines, and hoses
- Ice makers
- Air filters

Considerations in Plant Design

There are important considerations in the layout of the plant and the location of post-lethality processing. Cross-contamination can be avoided by separating raw meat and poultry from RTE products. Cross-contamination may also occur when raw unprepared vegetables contact ready-to-eat foods.

Air flow is another important concern. Air will flow from areas of high pressure to lower pressure. Air flow can be influenced by the location and operation of refrigeration units and other types of ventilation equipment. Air flow from a raw area into a cooked area could possibly carry *Lm* and contaminate the RTE product or product-contact surfaces.

An effective plant design will include sufficient **ventilation** to prevent the formation of condensation and control humidity.

Many different types of **plant layout** exist. It is the establishment's responsibility to control the processing procedures in whatever environment exists in its particular plant in order to ensure that only safe product is produced.

Examples of plant design considerations:

- Traffic between raw and RTE areas
- Physical proximity between RTE and raw products
- Air supply and flow between raw and RTE areas
- Humidity
- Overhead fixtures that harbor dirt or moisture
- Condensation
- Plumbing from drip pans

Environmental Testing

An environmental testing program can be a means of confirming that the establishment's controls are effective in maintaining a plant environment that will minimize the hazard of pathogens, including *Lm*. In addition to measuring the effectiveness of a sanitation program, a correctly designed environmental testing program may:

- Provide information about sources of environmental contaminants.
- Identify the extent of pathogen contamination of the environment.
- Provide information about faulty equipment design or operation.
- Identify probable post-processing cross-contamination sites.

The **design** of the testing program will vary depending on the purpose, the microorganisms tested for, the sampling method used, and the analytical methods. Some establishments will design their program for the purpose of measuring the effectiveness of the cleaning procedures; other testing programs might be designed to verify that finished product is free of a certain pathogen, for example, *Listeria monocytogenes*. Some establishments test for organic residues. Another establishment might test for non-pathogens, for example, yeast and mold, or coliforms. Other establishments might test for indicators of potential pathogens, such as *Listeria* spp. (see below). There are a wide variety of sampling methods used and many more are being developed. Some examples are: swabs and sponges used with standard plating methods, prepared plates and other testing kits of various types, and air collection systems. The amount of time it takes test results to be available also varies from several minutes to several days, depending on the type of method used.

***Listeria* spp. versus *Listeria monocytogenes*.** The term *Listeria* spp. (species) refers to all strains of *Listeria*. Because *Lm* is typically present only in very low numbers on RTE products, it can be difficult to detect with the available testing capabilities. Therefore, many establishments use a testing plan for *Listeria* spp. because it is easier and faster to find *Listeria* spp. since the testing is looking for more types of *Listeria*. Positive test results for *Listeria* spp. should be viewed as an indication that *Lm* may be present and alert the plant that there are generally undesirable conditions present in the facility. However, it should be kept in mind that from both a regulatory and public health standpoint, findings of *Listeria* spp. would not have the same level of significance as findings of *Lm*. Findings of *Listeria* spp. indicate that a pathogen may be present, but are not conclusive evidence of a pathogen. Findings of *Lm* are evidence of a pathogen. FSIS would anticipate that the company would initiate actions that address any positive findings of *Listeria* spp. as a means to ensure that product does not become adulterated with *Lm*.

Environmental surface testing is most often performed in the areas where exposed product is handled, such as in the post-cook processing and packaging areas, to discover where *Listeria* might be found. Examples are air handling units, walls, floors, and drains. Environmental testing results would be used to evaluate the effectiveness of sanitation programs and develop methods to improve them. Positive tests may indicate a problem with the sanitation program such that *Listeria* exists in the environment and may or may not have been transferred to product produced in that environment. Positive environmental tests should be followed up by thorough cleaning of suspect areas and by product testing to ensure product safety.

Food-contact surface testing includes any equipment or utensils that would come into contact with the exposed RTE product. Examples are slicers,

peelers, tables, and knives. A positive contact surface test implies that any finished product that has touched that surface may have become contaminated.

Product testing determines whether *Lm* is present on the product. Findings of *Lm* in finished product are significant evidence that *Lm* contamination may be a food safety hazard reasonably likely to occur in the production process for that product.

Recordkeeping is important in environmental testing programs. The results of environmental sampling are not available until after products are produced. Therefore, adequate and accurate records are essential because the environmental sampling program is of retrospective value only. For example, identification of the site sampled and the visible condition of the site is necessary to effectively utilize the sampling results.

Regulatory Requirements for Sanitation Standard Operating Procedures

The **Sanitation SOP regulations** (9 CFR Part 416) require each official establishment to develop, implement, and maintain written Sanitation SOPs that are to be followed before and during food production operations.

The regulation governing the **maintenance** of the Sanitation SOPs requires that the establishment routinely evaluates both the overall effectiveness of the SSOPs and the specific procedures employed in preventing direct contamination or adulteration of products. The establishment is required to revise these procedures as necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel. This is required by 9 CFR 416.14, which states:

“Each establishment shall routinely evaluate the effectiveness of the Sanitation SOPs and the procedures therein in preventing direct contamination or adulteration of product(s) and shall revise both as necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel.”

The Sanitation SOP **corrective action** regulation (9 CFR 416.15) requires that the establishment take appropriate corrective action when either the establishment or FSIS determines that the establishment’s Sanitation SOPs

overall, the specific procedures contained in the SSOPs or the implementation or maintenance of the SSOPs, may have failed to prevent direct contamination or adulteration of products.

Establishments that produce RTE products are responsible for ensuring on an on-going basis that their Sanitation SOPs are effective in preventing contamination and adulteration by *Lm* and other pathogens in the post-lethality environments.

It is particularly important that establishments that produce RTE products such as hot-dogs and deli meats conduct on-going evaluation of their control of *Lm* in the post-processing environment. Conducting environmental and product testing is an effective way to accomplish this evaluation.

Relationship Between Sanitation and HACCP in RTE Processes

For most RTE products, a CCP probably exists for thermal destruction of pathogens. Another CCP may need to be developed to address the prevention of post-process contamination of the product. In some cases, part of an SSOP may be transferred to the actual HACCP plan if those controls are determined to be critical to the production of a safe meat or poultry product, and there is no step later in the process which will control the hazard. This will depend on the hazard analysis and the method the plant decided to use for control of that hazard. For example, an establishment might have a CCP for the concentration and application of sanitizers, or for environmental testing as a verification of the effectiveness of cleaning and sanitizing programs. You will learn more about the application of HACCP in later parts of this training.

FSIS Verification

You will verify the effectiveness of the Sanitation SOPs, HACCP plan, and any other prerequisite program that addresses RTE sanitation. This may also include review of the establishment's environmental and product testing programs.

References

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- Guidelines for Developing Good Manufacturing Practices (GMPs), Standard Operating Procedures (SOPs) and Environmental Sampling/Testing Recommendations (ESTRs) Ready-to-Eat (RTE) Products, In Cooperation With North American Meat Processors; Central States Meat Association; South East Meat Association; Southwest Meat Association; Food Marketing Institute; National Meat Association; and American Association of Meat Processors, April 1999.

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Workshop

1. Mark T for “true” and F for “false” for each of the following statements

- a) ___ A locker room shared between RTE handlers and raw product handlers could be a source of RTE product cross-contamination.
- b) ___ RTE product which occasionally contacts the wall in the cooler is at risk for contamination with *Listeria monocytogenes*.
- c) ___ RTE products must be cooked by the consumer before they are eaten.
- d) ___ Periodically rotating sanitizers will provide greater effectiveness against bacteria.
- e) ___ *Listeria monocytogenes* is especially harmful to pregnant women and infants.
- f) ___ *Listeria monocytogenes* is fragile and cannot grow in refrigerated, packaged, RTE products.
- g) ___ *Listeria monocytogenes* can grow in cool, damp environments such as coolers and floors.
- h) ___ Plant construction has been linked to contamination with *Listeria monocytogenes*.
- i) ___ An environmental testing program can be a means of confirming that the establishment’s controls are effective in maintaining a plant environment that will minimize the hazard of pathogens.
- j) ___ Environmental testing could include sampling in the post-cook processing area to discover where *Lm* might be found.
- k) ___ An establishment finds *Lm* in finished product through product testing. FSIS would consider this to be evidence that *Lm* contamination may be a food safety hazard reasonably likely to occur in that plant’s processes.
- l) ___ Establishments are responsible for ensuring that their Sanitation SOPs are effective in preventing contamination by *Lm* in the post-lethality environment.

2. Case Study. (Please note, this is a simplified training example only.) You are assigned to a large RTE establishment that produces a variety of sliced, cooked ham products. Raw meats are extruded into a plastic bag, placed in a metal form, and cooked in a water bath. After cooking and cooling, the meat is removed from the bags, sliced, and sealed in 8-oz plastic film packages.

- a. From the standpoint of post-cooking contamination, why is the slicing area the most critical?

You observe the slicing process. The cooked meat is dumped out of the metal forms onto a stainless steel table by one person. A second worker opens the bags with a knife and removes the meat from the bags, pushing the unwrapped meat toward the other side of the table. In that area, a third worker places the meat into the slicer. The slicing equipment deposits the sliced meat into the packaging machine, where it is sealed into the film packages.

- b. List the potential product contact surfaces in this scenario.

This establishment is updating the equipment in one of the coolers. You decide to observe. You see that there is no product in the cooler and that construction workers, wearing frocks over their street clothes, are dismantling the fans, overhead refrigeration units, pipes, and drains. Other workers are replacing the material on the walls. There is debris from the construction scattered about. You observe a construction worker load some of the old materials and equipment onto a pallet and take it out through the only door. This door opens into the main hallway in this plant, used by all departments. There is no covering over the old equipment on the pallet. The other departments are working as usual.

- c. What concerns do you have about this situation? Please explain.

3. Case Study. (Please note, this is a simplified training example only.) You are assigned to an establishment that makes smoked turkey for slicing at delis. The establishment includes its *Listeria monocytogenes* control program in the Sanitation SOPs. The environmental monitoring component of this program targets the packaging room. This is where product is taken off of smokehouse racks, cut into halves, and vacuum packaged.

The establishment conducts routine **environmental** sampling. It has identified 20 sampling sites, including walls, drains, floors, etc. Each month it randomly picks 5 sites to test for *Listeria* spp. These sites are tested twice weekly before production begins.

- When a positive sample result is detected, that site is given extra attention during the next routine sanitation.
- If the same environmental site comes up positive for *Listeria* spp. twice in one month, it is re-swabbed daily until there are three consecutive days of negative test results. Once this has occurred, the plant reverts to routine monitoring.
- If the problem is not corrected within 5 days, the plant enters the “trouble-shooting” mode, which includes more stringent decontamination procedures, such as disassembly and sanitizing, fogging with sanitizers, changing sanitizers, double sanitizing, and heat treatments.

a. At what point are the environmental samples taken?

- ☐ before production begins
☐ after production ends

b. What action is taken when a positive is identified during random sampling?
(circle the information and mark it “b”)

c. What action is taken if the same environmental site comes up positive twice in one month?
(circle the information and mark it “c”)

d. What action is taken if the problem is not corrected after 5 days?
(circle the information and mark it “d”)

The establishment also conducts routine random **product contact surface** testing. It has identified 20 key product contact surface sites, such as table tops, packaging equipment, and knife blades. Each month 5 sites are randomly selected to be tested for *Listeria* spp. These sites are tested twice weekly, at the end of production before cleaning.

- If a positive sample result is detected, that site is given extra attention during the next sanitation and re-swabbed daily for 5 days.
- If the site is again positive for *Listeria* spp. during this 5-day period, the product contact surface is taken out of production and, if appropriate, torn apart, and trouble-shooting swabs are taken during the disassembly.
 - The product-contact surface and surrounding areas receive extra sanitation, and the item is re-assembled and placed back into production.
 - Product contact surface swabs are then taken every two hours during production.
 - All product is placed on hold until results are received.
 - If any swab tests positive for *Listeria* spp., product from that 2-hour time period and from each period on either side of the positive result is tested for *Listeria monocytogenes*.
 - Product that tests negative for *Lm* is released.
 - Product that tests positive for *Lm* is destroyed, since re-processing is not an option for this product.

e. At what point are the product contact surface samples taken?

___before production begins
___after production ends

f. What action is taken when a positive test result for *Listeria* spp. is identified during random sampling?

(circle the information and mark it "f")

g. What action is taken if the same site comes up positive for *Listeria* spp. again?

(circle the information and mark it "g")

h. When are product samples for *Listeria monocytogenes* taken?

i. What do you think is the purpose of the increased sampling and sanitation after a site is positive for *Listeria* spp. twice during a 5-day period?

j. Would you review records associated with this program? If so, when? Please explain your answer.

k. Would you observe employees performing the sampling procedures? If so, when? Please explain your answer.